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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,875	03/02/2002	Hans Schuhbauer	HUBR-1206 (10202655)	4984

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,875	SCHUHBAUER ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-33 and 35-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-33 and 35-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 9/16/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 27-31, 33-37,40-43 and 46-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ulrich et al (USPN 5,691,379 hereafter '379) and Richardson et al (USPN 6,207,190 hereafter '190). The claims are drawn to a sustained release formulation of α-lipoic acid and/or derivative, a cationogenic polymer and an additional acidic component. The formulation further comprises fillers, and other excipients well known in the art.

2. The '379 discloses a dihydrolipoic acid sustained release formulation comprising various biocompatible cellulosic polymers, acetic acid, and other fillers, lubricants and plasticizers known in the art (abstract; col. 48 – 64; col. 7, lin. 34 – col. 8, lin. 47). The formulation can be formed into medicaments such as capsules, pellets and pills, or in the form of a lotion (col. 9, lin. 42 – 48). The reference discloses methods for the administration of the formulation (col. 9, lin. 53 – col. 10, lin. 11). The formulation is granulated along with the carrier materials and processed at a temperature between 20 and 80 degrees Celsius (col. 10, lin. 23 – col. 11, lin. 3).

The reference however does not disclose chitosan as the catiogenic polymer, however chitosan is well known in the art, as seen in the '190 patent.

3. The '190 patent teaches a sustained release formulation comprising α-lipoic acid and various release retarding polymers (col. 20, lin. 15-28), such as cellulose derivatives and chitosan (col. 22, lin. 10-18). The reference establishes the equivalency between chitosan and other well-known polymers used in the '379 invention such as hydroxypropylmethylcellulose and methacrylic acid. A skilled artisan would be motivated to include the chitosan of the reference into the formulation of '379 since they share similar sustained release polymers.

4. With regard to claims 35, 36, 41 and 53, which recite limitations to specific concentrations, ratios and proportions, it is the position of the examiner that such limitations do not impart patentability on the claims barring a showing of criticality. The prior art discloses a general combination of the elements, and applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

5. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

6. With these things in mind one of ordinary skill in the art would have been motivated to combine the chitosan of '190 with the formulation of '379 in order to provide a sustained release formulation in order to provide the best biocompatible matrix. A skilled artisan would have also been motivated to optimize the concentrations and ranges of the reference in order to achieve the best result. It would have been obvious to a skilled artisan to follow the suggestions and teachings of the prior art, at the time of the invention, to combine the teachings with an expected result of a sustained release formulation with antioxidant, properties.

7. Claims 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ulrich et al (USPN 5,691,379 hereafter '379 and USPN 5,100,919 hereafter '919) and Richardson et al (USPN 6,207,190 hereafter '190). The claims are drawn to a sustained release formulation recited particular concentrations and proportions of the essential components, namely a cationogenic polymer, a α-lipoic acid and/or a derivative, and a further acid. The claims also are drawn to a method of production comprising combining the components along with other well known excipient such as filler, plasticizers and the like, wet granulating the combination and drying the granules between 5 and 50°C, an forming a tablet.

As discussed above the combination of Ulrich '379 and '190 discloses a combination that obviates the instant invention. The combination however discloses a much wider temperature operation range that that of the instant claims. It is the position of the examiner that though the reference does not disclose the particular proportions recited in the claims, a skilled artisan would still be motivated to follow the processing stapes of combining the active, with the excipients, granulating and drying them at a temperature between 20 and 80 °C, since wet

granulation and tableting are so well known in the art. Ulrich '919 discloses tablets formed from wet granulation of the ingredients and drying overnight at a temperature of 45 °C (examples).

As discussed above the proportion of the active and inactive components could be determined through routine experimentation. With this in mind a skilled artisan would have been motivated by the suggestion of Ulrich '379 to granulated and dry the granules at the desired temperature of Ulrich '919. It would have been obvious to combine the tablet the ingredients of Ulrich '379 with the process of Ulrich '919 with an expected result of a tablet with antioxidant properties.

8. Claims 32,38,39, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ulrich et al (USPN 5,691,379 hereafter '379) and Richardson et al (USPN 6,207,190 hereafter '190) in view of Weithman et al (USPN 5,318,987 hereafter '987); in view of Bethge et al (USPN 5,621,117 hereafter '117); in view of Prigal (USPN 3,678,149 hereafter '149); and in view of Matsuoka et al (USPN 3,697,647 hereafter '647). The claims are drawn to a pharmaceutical dosage form comprising a α-lipoic, a cationogenic polymer, and another acid. The α-lipoic acid can be present with cation such as iron, copper and palladium. The acid can be a Lewis acid, or a complex acid. The composition can be in the form of a food supplement as well.

As discussed above the '379 and 190 combination discloses essential elements of the claimed invention. The combination discloses α-lipoic compound, biopolymer and secondary acid. Lacking in the reference are disclosures of the specific cations present in the active compound salt, the complex or Lewis acids, and the food supplement presentation.

The '987 patent discloses an antioxidant composition comprising a α-lipoic acid derivative (col. 27, lin. 1). Cations present in the salts of the salts of the compound are alkaline earth metals such as zinc, iron and aluminum (col. 10, lin. 45 – 55). The composition further comprises further tableting excipients such as fillers sugars and tableting agents well known in the art (col. 12, lin. 5 – 34). A skilled artisan would have been motivated to combine these teachings in order to provide a more soluble formulation.

The '117 patent discloses a method for racemizing α-lipoic acid composition comprising inorganic and /or organic Lewis acids that are added to the α-lipoic compounds (col. 2, lin. 56 – 65; examples). A skilled artisan would have been motivated to combine the teachings and use the acid of '117 in order to properly solubilize the α-lipoic.

The '149 patent discloses a composition comprising hexacyanoiron in combination with antioxidants (col. 1, lin. 26 – col. 2, lin. 35; examples). A skilled artisan would have been motivated to combine the teachings and use the acid of '149 in order to properly solubilize the α-lipoic.

The '647 patent discloses a feed composition comprising α-lipoic compositions along with their cationic salts and other antioxidants (col. 12, lin. 19 – 30; examples). A skilled artisan would have been motivated to combine the teachings in order to impart antioxidant properties on consumables.

Taking the prior art not consideration a skilled artisan would have been motivated to combine the salts of '987 with the combination of '379 and '190 in order to improve the solubility; combined the acids of '117 and '149 in order to properly solubilize the α-lipoic acid compounds; and would have been motivated to include the resultant formulation into a food

composition as seen in '647 in order to impart antioxidant properties into consumables. It would have been obvious to a skilled artisan to combine the teachings and suggestions of the art with an expected result of food product where the α-lipoic acid compound is properly solubilized and has better bioavailability, and in turn has antioxidant properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
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